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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,627	12/08/2003	Brian D. Halevie-Goldman	306822 15566	4270

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,627	HALEVIE-GOLDMAN, BRIAN D.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *5-8,12,13,19,24,28-31,34,35,41 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9-11,14-18,20-23,25-27,32,33,36-40 and 42-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040308;20050314*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 5-8, 12, 13, 19, 24, 28-31, 34, 35, 41, and 45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 14, 2005.

Applicant's election with traverse of the opiate destruction inhibitor hydrocinnamic acid, the neurotransmitter precursor L-phenylalanine, and the cofactor N-acetyl-tyrosine in the reply filed on March 14, 2005 is acknowledged. The traversal is on the ground(s) that there is no serious burden on the examiner to search all of the claimed invention. This is not found persuasive because the various claimed opiate destruction inhibitors, neurotransmitter precursors, and cofactors all have patentably distinct structures from one another. Because searching in the chemical composition art is performed primarily on the basis of chemical structure, searching multiple patentably distinct structures constitutes an undue burden on the examiner. For example, Applicants note that hydrocinnamic acid and phenylalanine differ by only a single amino acid group. However, this difference results in a different classification for the two compounds (514/570 and 562/496 for hydrocinnamic acid, and 514/567 and 562/445 for phenylalanine), which is further evidence of an undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant's preliminary amendment filed March 14, 2005 is in improper format under 37 CFR 1.121(c). Note that claims 10, 17-19, 22, 23, 28, 29, 32, 35, 36, 38-42, and 44 use an incorrect status identifier, instead of the correct "(Previously presented)".

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)).

4. The disclosure is objected to because of the following informalities: The status of the non-provisional U.S. patent application referred to at page 6, line 5, and page 9, line 5, of the specification should be updated. Appropriate correction is required.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

6. Claims 1-4, 9-11, 14, 16-18, 20-23, 25-27, 32, 33, 36, 38-40, and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Blum (U.S. Patent No. 6,132,724). Blum teaches compositions comprising an opiate destruction inhibitor such as D-phenylalanine, hydrocinnamic acid, and DL-phenylalanine; at least one neurotransmitter precursor selected from the dopamine precursors L-Tyr, L-Phe, and L-dopa, the serotonin precursors L-Trp and 5-hydroxytryptophan, and the GABA precursors L-Gln, L-Glu, and L-glutamate; and a tryptophan enhancing amount of chromium picolinate or chromium nicotinate. Specific compositions comprise DL-phenylalanine in amounts of 250-500 mg, tyrosine in amounts of 25-150 mg, hydroxytryptophan in an amount of 2.5 mg, and L-Gln in amounts of 15-52 mg. Administration prior to exercise is taught in Example 1. See, e.g., the Abstract; column 72, lines 44-46; column 82, line 55 - column 83, line 5; Tables 6-16; column 97, lines 33-37 and 65-67; and claims 1 and 5. Because the same active agents are being administered to the same patients by the same method steps, inherently the natural reward system for exercise in the patient and the patient's energy will be enhanced in the method of Blum to the same extent claimed by Applicant. Because the same active agents are present in the same composition, inherently the compositions of Blum will be at least as effective as Ephedra in increasing energy in a patient as is claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the compositions and methods of Blum and Applicant's claimed compositions and methods to shift the burden to Applicant to provide evidence that the claimed compositions and methods are unobviously different than those of Blum. With respect to Applicant's composition claims, note also that an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art.

7. Claims 1-4, 9-11, 14-18, 25-27, 32, 33, and 36-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Ehrenpreis et al (U.S. Patent Application Publication 2004/0241256). Ehrenpreis et al teach compositions comprising D-phenylalanine and/or hydrocinnamic acid and a dietary food supplement comprising L-tryptophine (sic - L-tryptophan), Ephedra, glutamine, and Tyrosine. The compositions are administered orally, and can be administered to reduce pain accompanying athletic exercise and to improve endurance, strength, and performance. See, e.g., paragraphs [0015], [0017]-[0020], [0023]-[0025], and [0039]. The D-phenylalanine and hydrocinnamic acid corresponds to Applicant's opiate destruction-inhibitor; the L-tryptophine corresponds to Applicant's serotonin precursor; the glutamine corresponds to Applicant's GABA precursor and to Applicant's cofactor; and the Tyrosine corresponds to Applicant's dopamine precursor. Because the same active agents are being administered to the same patients by the same method steps, inherently the natural reward system for exercise in the patient and the patient's energy will be enhanced in the method of Ehrenpreis et al to the same extent claimed by Applicant. Because the same active agents are present in the same composition, inherently the compositions of Ehrenpreis et al will be at least as effective as Ephedra in increasing energy in a patient as is claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the compositions and methods of Ehrenpreis et al and Applicant's claimed compositions and methods to shift the burden to Applicant to provide evidence that the claimed compositions and methods are unobviously different than those of Ehrenpreis et al. With respect to Applicant's composition claims, note also that an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art.

8. Claims 20-23 and 42-44 are rejected under 35 U.S.C. 103(a) as being obvious over Ehrenpreis et al (U.S. Patent Application Publication 2004/0241256). Application of Ehrenpreis et al is the same as in the above rejection of claims 1-4, 9-11, 14-18, 25-27, 32, 33, and 36-40. Ehrenpreis et al do not teach Applicant's claimed daily dosages. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal daily dosages for the components present in the compositions of Ehrenpreis et al because dosage is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical and nutritional supplement arts, and because Ehrenpreis et al disclose the need to optimize dosages (see, e.g., paragraphs [0023] and [0039]).

9. Claims 1-4, 9-11, 16-18, 25-27, 32, 33, and 38-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Chinery (U.S. Patent Application Publication 2004/0077556). Chinery teaches compositions comprising dl-methionine, N-acetyl-tyrosine, and l-tyrosine. The compositions are used to boost energy levels in mammals, are at least as effective as Ephedra, and can be administered as part of an exercise program. See, e.g., the Abstract; paragraphs [0008] and [0391]; and Examples 1-3. Chinery's d-methionine, which is present in dl-methionine, corresponds to Applicant's opiate destruction-inhibitor which is a D-form mono amino acid. Chinery's l-tyrosine corresponds to Applicant's neurotransmitter/dopamine precursor. Because the same active agents are being administered to the same patients by the same method steps, inherently the natural reward system for exercise in the patient and the patient's energy will be enhanced in the method of Chinery to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the compositions and methods of Chinery and Applicant's claimed compositions and methods to shift the burden

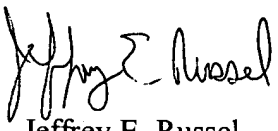
to Applicant to provide evidence that the claimed compositions and methods are unobviously different than those of Chinery. With respect to Applicant's composition claims, note also that an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art.

10. Claims 20, 22, and 42 are rejected under 35 U.S.C. 103(a) as being obvious over Chinery (U.S. Patent Application Publication 2004/0077556). Application of Chinery is the same as in the above rejection of claims 1-4, 9-11, 16-18, 25-27, 32, 33, and 38-40. Chinery does not teach Applicant's claimed daily dosages. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal daily dosages for the components present in the compositions of Chinery because dosage is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical and nutritional supplement arts

11. Bieser et al (U.S. Patent No. 6,159,506) is cited as art of interest, being essentially duplicative of the references applied above.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

April 25, 2005